AMERICAN SEED TRADE ASSOCIATION

January 24, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004D-0369

Sent Via: http://www.fda.gov/dockets/ecomments

Dear Sir/Madam:

The American Seed Trade Association (ASTA) has members that are involved, directly or indirectly, in the development and licensing of seeds and seed technologies including modern biotechnology that have food and other applications. Given its widespread adoption, modern biotechnology is impacting the U.S. seed industry. We, therefore, appreciate the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance entitled, "Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties for Food Use."

Founded in 1883, the American Seed Trade Association, located in Alexandria, Virginia, is one of the oldest trade organizations in the United States. Its membership consists of approximately 850 companies involved in seed production and distribution, plant breeding, and related industries in North America. As an authority on plant germplasm, ASTA advocates science and policy issues of industry importance. Its mission is to enhance the development and free movement of quality seed worldwide.

ASTA supports the FDA policy framework and draft guidance for early evaluation of food and feed crops with new non-pesticidal proteins derived from recombinant DNA techniques that are stringent and sufficiently restrictive to protect human health. However, ASTA believes that FDA's definition of bioengineered or recombinant DNA plants is too broad. The definition includes, for example, the direct injection of nucleic acids into cells, even if the nucleic acids do not involve recombinant DNA. We suggest the adoption of a more precise definition and one that is consistent with that of the Environmental Protection Agency pertaining to plant incorporated protectants that are proteins. *See* 40 C.F.R. §174.3 (2004)

ASTA also supports the process and proposed collection of information as indicated in the FDA's draft guidance. We believe that such guidance is necessary for the proper performance of FDA's functions and that the information will have practical utility in the earlier determination of food safety of plants containing new non-pesticidal proteins derived from

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recombinant DNA techniques. The process of consultations between FDA and industry involved in the development of bioengineered plants has worked well since 1992 when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties. These consultations have addressed potential food safety issues pertaining to allergenicity and toxicity of new plant varieties derived through recombinant DNA techniques during early development.

Future FDA consultations with industry on early food safety evaluations will continue to help ensure that industry's market entry decisions, which include considerations relative to low level incidental presence of new non-insecticidal proteins not yet approved for commercial use, are made consistently and in full compliance with the standards of the Federal Food, Drug, and Cosmetic Act (the Act). Procedures contained in the draft FDA guidance and information gained through FDA's early food safety evaluations can only enhance effort by developers of new human and animal foods to ensure the foods that they offer to consumers are safe and in compliance with all requirements of the Act. We believe that the FDA guidance will further enhance the level of cooperation between FDA and industry.

The FDA draft guidance is also a positive step forward in meeting the objectives stated by the Office of Science and Technology Policy (OSTP) in its August, 2002 notice on the low level intermittent presence in food and feed of new non-pesticidal proteins. The U.S. seed industry fully recognizes that marketing and regulations must remain consistent with advancements in new agricultural technologies. The actions proposed by FDA will help maintain science-based regulations and will serve to maintain confidence of domestic and international customers of the seed industry, feed and food product users, as well as consumers.

ASTA also believes that FDA's draft guidance provides an extra measure of clarity on the FDA's process of safety evaluations for new non-insecticidal proteins. The FDA review process recognizes that traits not yet approved for commercial use but meet a specific set of food safety criteria may be allowed in seed, grain or food marketed in the United States. The FDA draft guidance allows for the continued development and rigorous evaluation of important technologies such as new traits developed through modern biotechnology. In addition, it fundamentally contains science-based criteria for food safety assessment of adventitious presence in seed for planting and recognizes general risk-based categories for both the crop and new non-insecticidal proteins. The FDA draft guidance also allows for the earliest assessment of data relative to, among other things, the encoded protein, intended compositional change, and experience with the host crop/trait/protein at an appropriate stage in field-testing by the developer.

Most importantly, the seed industry continues to face disruptions to trade due to uncertainty around of low levels of modern biotech events or adventitious presence (AP) in conventional and biotech seed products intended for ultimate use in the production of food and feed products. There remains an urgent need to establish a scientific basis to allow for low level incidental presence of material not yet approved for commercial use, so that this may be a component of intergovernmental discussions on trade. While resolution of international AP issues is not a stated objective of the FDA draft guidance for early food safety evaluation, the development of the FDA guidance, nonetheless, may support U.S. government consultations on modern biotechnology globally and possible international acceptance of adventitious presence of new

non-pesticidal proteins deemed safe by FDA in conventional seed lots.

Lastly, ASTA believes that since imported foreign-developed GM products must meet the same safety standards that apply to comparable domestic products, FDA should consider mutually-recognized expedited food safety evaluations of GM food and feed commodities and work towards harmonizing validated data collection with countries that export GM food and feed to the United States.

ASTA and its members appreciate the opportunity to comment on the FDA draft guidance and would be pleased to further discuss these comments. As the process moves forward, we encourage future opportunities to provide a U.S. seed industry perspective on these and other issues relative to the regulation of modern biotechnology-derived products.

Sincerely,

Richard T. Crowder
President/CEO
American Seed Trade Association